National Institute on Drug Abuse
National Advisory Council on Drug Abuse
Workgroup on HIV/AIDS
Findings and Recommendations

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Center For Urban Epidemiologic Studies

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National Advisory Council on Drug Abuse
National Institute on Drug Abuse
6001 Executive Blvd.
Bethesda, MD 20892

Dear Council Members:

On behalf of the Workgroup on HIV/AIDS, I am pleased to submit this final report of Findings and Recommendations to the National Advisory Council on Drug Abuse. This report responds to the charge by the Director, NIDA, to the Council to review NIDA's HIV/AIDS research portfolio for responsiveness to emerging trends and to assess the appropriateness of NIDA's plans to advance the science. The charge also included addressing NIDA's relationships with other NIH institutes and agencies, as well as the organization and management within NIDA.

The Workgroup members have unanimously approved the report, which presents discussion of pertinent issues and recommendations responsive to the charge. I appreciate the opportunity to participate in this Workgroup and thank the members for their professionalism and hard work. I am confident that the suggestions contained herein will prove very valuable in furthering NIDA's research in HIV/AIDS.

Sincerely,

David Vlahov, Ph.D.
Chair, Workgroup on HIV/AIDS
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Final Report: November 14, 2003

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Executive Summary

The Director of the National Institute on Drug Abuse (NIDA), Nora Volkow, MD, charged the NIDA National Advisory Council on Drug Abuse Workgroup on HIV/AIDS with the following:

- Review NIDA's HIV/AIDS research portfolio to ensure that it is responsive to emerging trends and new findings and assess whether future plans are appropriate to advance the science. In particular, are the projects we are funding examining the most important factors to prevent and/or treat the consequences of HIV/AIDS in drug abusing populations?

- Review the Center on AIDS and Other Medical Consequences of Drug Abuse's (CAMCODA) interactions with other NIDA divisions and centers as well as NIDA's relationships with other NIH institutes and agencies. For example, how can the National Drug Abuse Treatment Clinical Trials Network (CTN), the NIDA medications development program, or networks supported by NIAID, be best used to address relevant HIV/AIDS research questions?

- Examine CAMCODA's organization and management to make sure that its infrastructure is optimal to carry out its mission in the most efficient fashion.

- Help to define a 5-year vision of NIDA's HIV/AIDS research portfolio.

These specific charges were redefined into two areas by the members of the Workgroup: (1) portfolio content and (2) infrastructure, processes, and interactions. Specific findings on CAMCODA's organization and management were also addressed.

The Workgroup summarizes its response to the charges regarding portfolio content by stating that NIDA's HIV/AIDS portfolio has considerable breadth, but is less impressive in depth in HIV/AIDS research. Although the Workgroup proposes several specific areas for research, the general consensus was that NIDA should strive for a forward-looking portfolio that addresses the unique dimensions of drug use and abuse as they relate to HIV/AIDS. In addition, the research portfolio should be guided by the epidemiology of the HIV/AIDS pandemic, the evolution of HIV/AIDS diagnoses and treatment, and the role of drug abuse and related behaviors in HIV/AIDS. For both domestic and international research, greater attention to these factors is warranted. The research portfolio also should incorporate various perspectives about the determinants and consequences, as well as prevention, management, and treatment, of HIV/AIDS. The portfolio should reflect biomedical, behavioral, and social research approaches.

In considering infrastructure, processes, and interactions, there was general consensus among Workgroup members that adequate leadership is lacking in planning and coordinating HIV/AIDS research across Divisions, Centers, and the Intramural Research Program of NIDA, as well as with outside parties. The Workgroup also noted that the issue is complicated by the inherent conflict from the organizational decision that created a dual mission for CAMCODA, which is to provide leadership and stimulate research across NIDA for the development of other Divisions' portfolios, but also to maintain its own HIV/AIDS portfolio. The Workgroup also concluded that ineffective management within CAMCODA affects planning and the accomplishment of goals. Workgroup members recommend that NIDA establish a coordinator for HIV/AIDS research who will report directly to the NIDA Director and whose primary responsibility will be the planning, development, and coordination of priority research within NIDA intramural and extramural programs, as well as with other relevant institutes and agencies, to achieve an integrated vision and program for HIV/AIDS research throughout NIDA. A second recommendation is to establish or maintain a separate entity, at the administrative discretion of NIDA, with a focus on the medical consequences of drug use.

I. Introduction

A. Description of the HIV/AIDS Program and Portfolio at NIDA

In Fiscal Year (FY) 2002, NIDA received approximately $260 million in AIDS funding. In FY 2003, NIDA's AIDS budget increased to approximately $304 million, or 31 percent of the total NIDA budget. Of the other NIH Institutes, only the AIDS budget of the National Institute of Allergy and Infectious Diseases (NIAID) surpassed NIDA's budget in total dollars in FY 2003. By far the largest amount of NIDA AIDS funding in both FY 2002 and 2003 (approximately $105 million each year) was allocated to CAMCODA. The presentation to the Workgroup by CAMCODA staff indicated that the HIV/AIDS portfolio was distributed to the following areas: behavioral and social sciences (50%); etiology and pathogenesis (21%); natural history and epidemiology (15%); training and capacity building (7%); therapeutics (6%); and information dissemination (1%).

The size of NIDA's HIV/AIDS research program underscores the enormous trust given to the Institute for the responsible stewardship of resources. Of primary importance is that NIDA's HIV/AIDS research program must be relevant to HIV/AIDS and drug use epidemics and to NIDA's mission. Each NIDA Division or Center's research program must be non-duplicative of research conducted by other NIH Institutes or NIDA components, and must focus on questions at the cutting-edge of science rather than exhausted scientific questions. The NIDA HIV/AIDS research program must be forward-looking and meaningful in the context of the overall NIH effort. Staffing expertise also should be proportionally commensurate with the expertise needed to manage the research portfolio in their respective areas.

B. Information Gathering

The Workgroup met on September 3-4, 2003, and held two follow-up conference calls on October 8 and October 28, 2003. In August, NIDA Divisions and Centers, including the NIDA Intramural Research Program (IRP), and selected NIH Institutes were asked to provide background materials for the Workgroup members and (except for the IRP) to make brief presentations at the September meeting on the following areas:

- A statement of vision for the next 3-5 years based on current and anticipated needs.

- A summary of the current status of the research portfolio or intramural research programs in HIV/AIDS.

- An organizational description that focuses on expertise needed in terms of research requirements.

On September 3-4, staff from the following NIDA Divisions and Centers made presentations before the Workgroup:

- Center on AIDS and Other Medical Consequences of Drug Abuse (CAMCODA)
- Division of Neuroscience and Behavioral Research (DNBR)
- Division of Treatment Research and Development (DTRD)
- Center for the Clinical Trials Network (CCTN)
- Division of Epidemiology, Services, and Prevention Research (DESPR)

Staff from the following NIH Institutes also made presentations to discuss opportunities for collaboration with NIDA on HIV/AIDS-related studies.

- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Mental Health (NIMH)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Before the meeting, all NIDA staff members were given the opportunity to respond to an e-mailed survey requesting ideas for future directions for NIDA's HIV/AIDS research and ways to optimize research administration. Responses could be submitted anonymously, and indication of the respondent's Division, Center, or Office was optional. Staff responded from at least five Divisions, Offices, or Centers within NIDA. As part of the survey, individuals were given the opportunity to request to meet with members of the Workgroup. Individual meetings with Workgroup members were held with those NIDA staff that requested meetings.

C. Scope of the Workgroup Effort

The Workgroup was constituted to represent a broad range of expertise in clinical science, basic science, epidemiology, behavioral and social science, prevention research, and other aspects of drug abuse. Laboratory, community, quantitative, and qualitative approaches to HIV/AIDS were represented. Workgroup members quickly realized that

the breadth and depth of issues reflected in NIDA's HIV/AIDS program would require a larger and more diverse group, and a longer timeframe than was available, to effectively address all the specific scientific areas and issues. Rather than attempt an exhaustive evaluation of all scientific areas, they chose to identify large, overarching themes and to address particularly noteworthy trends and issues of longstanding concern or promise.

Workgroup members included investigators who are supported by some of the programs being evaluated. While all members attempted to be dispassionate and objective, this issue of support was acknowledged in the Workgroup and here should be noted.

II. Findings

A. Responsiveness of NIDA's HIV/AIDS Portfolio to Emerging Trends and New Findings and Appropriateness of Future Plans to Advance the Science

The presentations and background materials indicated that the NIDA Divisions and Centers and NIH Institutes are dedicated to advancing a portfolio that addresses a wide range of appropriate areas in HIV/AIDS research and to building an HIV/AIDS research infrastructure. However, as a result of the weaknesses identified in the process for planning and coordination described below (under Section II. B), the Workgroup found a corresponding weakness in the current ability of NIDA to review and prioritize research in a manner that is fully responsive to emerging trends and new findings. The Workgroup summarized its findings on substantive HIV specific or related research topics in five sections: 1) the research portfolio could benefit from more attention to addressing the changing nature of and response to the HIV epidemic, as reflected in epidemiologic studies and other research advancing the understanding of HIV/AIDS; 2) international research on HIV/AIDS should target countries in which HIV/AIDS is linked to drug use or where this link can be prevented; 3) interdependence of HIV and drug abuse prevention and treatment must be considered; 4) challenges facing specific program areas need to be addressed; and 5) translational research is needed.

1. Better utilization of epidemiologic and other findings from the United States: A key point for consideration is the need for NIDA's HIV/AIDS research to be consistent with the epidemiology of HIV/AIDS and to incorporate various perspectives about the determinants and consequences of the disease. This would encompass biomedical, behavioral, and social approaches. In particular, with the declining incidence of HIV/AIDS among injection drug users in the United States, both the Centers for Disease Control and Prevention (CDC) and the NIAID have noted directions for additional research that reflect a more mature stage of the HIV/AIDS epidemic. While HIV/AIDS epidemiological studies indicate that new HIV/AIDS infection must continue to be an important focus of NIDA's portfolio, additional emphasis is needed for research efforts in the U.S. on case-finding and treatment of HIV seropositive persons, behavioral and medical interventions to optimize adherence and prevent drug resistance, and prevention of transmission to uninfected individuals through relapse of high risk drug and sexual behaviors due to the false perception of reduced infectivity with treatment. How these goals can be achieved in persons when they use drugs needs close attention, and NIDA gathers the expertise that can address these issues. While NIDA has led or contributed to

the considerable advances that have been made with regard to reducing risk of parenteral transmission of HIV, the understanding of sexual behaviors and HIV/AIDS infection among persons who use drugs is less developed. This necessitates research attention to be directed at the sexual risk behavior of drug users and their partners, and interventions to reduce risk. Drug users may be located in many different settings that provide opportunities for intervention research, and studies on specific factors relevant to transmission by HIV seropositive individuals are needed.

In addition, responding to the drug use aspects of the HIV epidemic requires that there be regularly updated links to information that emerges from groups doing substance abuse epidemiology, and that such information be used to update research directed at understanding HIV transmission, progression, treatment, and related issues. The understanding of the range of drugs and drug-associated behaviors that affect HIV/AIDS risk is continually evolving. Workgroup members noted that NIDA has expanded perspectives on the relationship of drugs to HIV infection, addressing not only injection of heroin and cocaine but also other routes of administration and other illicit drugs. Crack cocaine, inhaled heroin and cocaine, and more recently, amphetamines are being studied. An initiative on club drugs was launched in recognition of their inherent dangers and their putative association with HIV risk. Ecstasy is receiving increased focus in the NIDA portfolio, and research attention is turning towards the HIV risk associated with Viagra. NIDA staff reported a growing emphasis and interest on the HIV/AIDS consequences of other emerging drugs. This is an area where even more emphasis on relationships to HIV/AIDS transmission and progression can be placed. Stimulant drug users, bathhouse frequenters, men-who-have-sex-with-men, and other marginalized groups not reached by strategies aimed at the general population and whose risk is associated with drug use should be further addressed in studies. While this paragraph has emphasized the unique role that NIDA plays in tracking and studying emerging drugs in relationship to HIV infection, the Workgroup noted that there are drugs that have been around for years, e.g. marijuana , for which information about risk of HIV transmission, progression and response to HIV treatments needs to be improved.

The Workgroup concluded that a research portfolio that better mirrors the direction of the HIV/AIDS epidemic among drug-using populations, particularly adolescents and young adults, will be important to achieve. Additionally, as the drugs of abuse by at-risk populations change, the primary and secondary prevention measures must also change, incorporating and integrating findings about the populations, the contextual determinants of risk, and the pharmacologic properties of the drugs themselves.

2. International research and networks: Reviewing the international perspective on HIV/AIDS at NIDA, several observations were made: 1) NIDA has had an historic leadership role in networking countries to facilitate exchange of science. 2) The current and projected NIDA program in international HIV/AIDS research needs articulation. 3) The epidemiology of HIV infection indicates the international and global dimensions that need to be addressed. 4) For NIDA's participation in trans-NIH networks to have influence on the research activities led by other NIH components, it needs to demonstrate commitment and establish mutually understood roles and methods of ensuring input.

First, the Workgroup acknowledged NIDA's historic instrumental role in international HIV/AIDS research. One example of NIDA's recognition of the importance of developing an international research infrastructure in HIV/AIDS was its creation of the Global Research Network (GRN) on HIV Prevention in Drug-Using Populations in collaboration with the World Health Organization's Programme on Substance Abuse and the Joint United Nations Programme on HIV/AIDS. This was groundbreaking work.

Second, the rationale for parts of the current and projected NIDA international HIV/AIDS research portfolio was not clear. The HIV/AIDS epidemic among drug users is prominent in Southeast Asia (especially now in China and India) and eastern Europe/former Soviet Republics, and opportunities for research in these countries deserve attention. While South Africa and The Caribbean are important areas in the HIV pandemic, the reasons for selecting South Africa and the Caribbean as areas of emphasis within the NIDA portfolio were not made clear. This is the case, in part, because the presentations of the role of drug abuse in the HIV/AIDS epidemics in the Caribbean Basin and Sub-Saharan Africa were not clear. Building a case for the potential of drug use related HIV within these countries and considering the potential public health significance to the United States needs to be developed further. The international portfolio is very important, and limited funding dictates that the focus in this area must be on very unique research and on where drug abuse issues intersect with HIV/AIDS.

Third, the Workgroup agreed that the current approach to NIDA's international HIV/AIDS research could be made more responsive to the priorities identified in NIH and NIDA planning documents. To help articulate an international perspective, the Workgroup noted as background that the HIV epidemics can be viewed in stages, including "potential," "emerging," "explosive," "raging," and "maturing". It is accepted that the HIV epidemic has been and continues to be important in sub Saharan Africa, and that there have been newer, explosive epidemics in Asia and Russia/Eastern Europe. As noted above, the epidemics of North America and Western Europe are classified as more mature. Recent attention has focused on areas in the Western hemisphere where HIV is or may become a problem and where the intersection with drug abuse is potential. Approaches to prevention and control and opportunities for research vary with different stages of an HIV epidemic. For example, while population based prevention of uninfected persons have been used in emerging epidemics, case-finding, treatment and counseling of HIV seropositives are seen as more important in more mature epidemics. If the involvement of substance use is taken into consideration (which is relevant to NIDA), then certain countries where HIV is now raging or emerging appear more important to consider: namely, Russia, Eastern Europe, China, and India. In contrast, the epidemic in Africa has been considered to be due primarily to heterosexual activity, although more recently, exploration for information about substance use has started to emerge. Clearly, an emerging role of substance use in HIV epidemics in Africa and the Caribbean would be important to monitor and address.

While staging of epidemics is important for prioritization, the Workgroup noted that opportunities for important research would be missed if NIDA restricted its research to

locales where the HIV/AIDS epidemic is already "full blown" and intertwined with drug abuse. As examples, NIDA's role in studying HIV/AIDS in countries such as China and Russia is clear but reasons for NIDA's involvement in other areas are less clear and need to be articulated to justify continued investment in those regions. It may be that opportunities exist in other regions (*e.g.*, sub-Saharan Africa) to explore and study the role of substance abuse and its interactions/modifications of several conventional risk factors that have fueled the epidemic, ranging from STDs to use of traditional agents. Of specific note is that substance abuse is on the rise in countries such as Ethiopia and Nigeria (and possibly others) that are emerging to represent the next wave of HIV/AIDS infections.

The Workgroup members were somewhat concerned with some of the sites chosen for international emphasis, but they were much more concerned with an absence of articulated priorities and rationales for the selections. Sufficient perspective has been gathered from the decades of HIV/AIDS research to identify and distinguish at least some of the areas where the epidemic is "raging," "explosive," "emerging," or still only "potential," and the staff presentations did not sufficiently reflect consideration of the research potential within the developmental stages and trajectories of the respective epidemics. The HIV/AIDS epidemic and the drug abuse epidemic have evolved with different degrees of interdependence in different populations and locations, and NIDA's research should reflect careful consideration of the stage of each epidemic's evolution and a systematic approach to developing understanding at all stages.

To be more responsive and integrated with the rest of the NIH, NIDA participates in the existing NIH networks such as the HIV Prevention Trials Network (HPTN), the HIV Vaccine Trials Network (HVTN), and the AIDS Adult Clinical Trials Group (AACTG). NIDA has participated in other large scale observational epidemiologic studies domestically (e.g., the Women's Interagency Health Study (WIHS), the Women and Infants Transmission Study (WITS), to name a few. Other opportunities exist for collaboration with training networks supported through the Fogarty International Center. NIDA can assist in efforts to support and provide the clinical expertise for the training of health care professionals in the management of drug abuse. This is almost completely lacking in places such as sub-Saharan Africa. Other non-NIH networks could also be utilized as they are identified (*e.g.*, through CDC activities). NIH networks already exist in most of the settings of importance to NIDA's mission, including Southeast Asia and Russia. These networks also cover an extensive research agenda involving both HIV prevention and vaccine in sub-Saharan Africa, the Caribbean, and South American countries. Presentations from NIDA staff and other Institute staff indicated that NIDA has participated in some trans-NIH initiatives and networks, with varying degrees of investment, involvement, and input into the direction of the research. In some cases, NIDA's commitment to these initiatives was not clear and consistent; in other cases, there was clear commitment. For NIDA to have influence on the research activities led by other NIH components, it needs to demonstrate commitment and establish mutually understood roles and methods of ensuring input.

3. Interdependence of HIV/AIDS and drug abuse: The Workgroup noted two major and related concerns with NIDA's approach to the interdependence of HIV/AIDS and drug abuse. The first of these concerns is that the Institute has yet to fully develop and implement principles for distinguishing HIV/AIDS research from other research on non-HIV-related drug abuse. The second concern is that more and better research models that integrate HIV/AIDS and drug abuse perspectives are needed.

Distinguishing HIV/AIDS specific and HIV/AIDS-related research from other research on drug abuse can be considered both an administrative and scientific challenge, and it is therefore addressed here and under sections on coding and funding. Presentations to the Workgroup provided a consistent message that NIDA's policy is liberal in labeling research to develop and evaluate treatment for drug abuse as HIV/AIDS prevention or HIV/AIDS related. Similarly, development and evaluation of primary prevention for drug use are also widely considered HIV/AIDS prevention. Divisions responsible for drug abuse treatment development and testing noted that to some degree, substance abuse treatment is HIV prevention. Over time, this view has evolved to include standard HIV/AIDS risk assessments that have been added to ongoing drug abuse treatment protocols, so that evaluation of treatment with HIV behavioral outcomes provides some justification for considering these as HIV/AIDS studies and the use of AIDS funds for their support.

The Workgroup believes that in assigning HIV/AIDS funding to drug prevention and treatment research, it is necessary to ensure that this research makes meaningful and significant contributions to HIV/AIDS research and that HIV/AIDS components are fully integrated. Study protocols that merely include perfunctory questions about HIV/AIDS-related risk do not qualify, especially because those questions (and larger risk assessment instruments) do not appear to be standardized across NIDA studies and it is not entirely clear that the research may qualify as HIV related. Making the distinction between research activities to be labeled as HIV/AIDS and those that will not is a highly complex undertaking, and research findings suggest that HIV/AIDS risk reduction often is most effective within a broad context (*e.g.,* studies of adolescent high risk takers that find HIV/AIDS risk reduction interventions are more effective when provided in a context of reducing risk taking in general; findings that methadone treatment has some protective effects against HIV/AIDS). An overly restrictive or reductionist approach to HIV/AIDS definition does not fit well with the complexity of human behavior, nor the mission of NIDA. Drug abuse treatment and prevention research lie on a continuum of relevance to HIV/AIDS research; to be most effective in having an impact on HIV/AIDS (and thus qualify for AIDS dollars), studies should include a specific HIV/AIDS aspect and make a meaningful contribution toward understanding HIV/AIDS issues.

There also is a need for more and better research models that integrate drug abuse and HIV/AIDS issues. As noted, one way to do this is to include HIV/AIDS components in studies. HIV/AIDS relevant independent and dependent variables can be incorporated in studies to elucidate a number of issues related to prevention and treatment of drug abuse, HIV/AIDS, and other consequences of drug abuse. Given the strong association between drug use and HIV/AIDS risk, the Workgroup thought that targeting HIV/AIDS in an

integrated fashion, or at least as an integrated component, in all drug prevention and treatment research should be highly encouraged.

The Workgroup also recognized that NIDA staff plays an important role in stimulating research that integrates drug abuse and HIV/AIDS concerns, and they noted a need for more HIV/AIDS expertise at NIDA. This resulted in a recommendation that all Divisions and Centers should make acquiring and maintaining HIV/AIDS expertise a priority. Without sophisticated appreciation of the intersection of these scientific areas, it will not be possible to develop the needed, more nuanced, approach that takes into account the changing epidemiology of HIV/AIDS as well as the changing technologies to prevent, diagnose, and treat HIV/AIDS infection. This integrative approach needs to form the foundation for annual reviews and updates of NIDA's HIV/AIDS portfolio. Two particular aspects of integrated expertise need closer attention: (1) building HIV/AIDS expertise at NIDA and (2) making this HIV/AIDS expertise available and accepted as part of the scientific and organizational culture at NIDA. This is critical to developing integrated science within NIDA as well as to helping NIDA's drug experts communicate with HIV/AIDS colleagues at the rest of the NIH who are not familiar with addiction and do not appreciate the influence of substance use on HIV related risk and treatment. Similarly, mechanisms need to be in place to ensure that NIDA staff primarily involved in HIV/AIDS activities maintains currency in knowledge of broader drug abuse issues. Strong integration of both drug abuse and HIV/AIDS expertise is needed throughout NIDA's HIV/AIDS program.

*4. **Specific Program Areas***: The role of **family (defined broadly as a network of mutual support), social network and community level factors** should be encouraged. In terms of descriptive, analytic and intervention research relating to HIV prevention and treatment within NIDA, important work beyond individuals as the unit of analysis to encompass family and drug network relationships is already supported, and the approaches represented are innovative. Work at the neighborhood and community level and other social factors have begun to emerge in the portfolio, and this represents an important direction for development that is reflective of the needed research directions in HIV/AIDS. Examples of this are studies of the role of networks in HIV prevention, the role of families in medication adherence, the diffusion studies that are being initiated in CAMCODA under a cooperative agreement to address determinants and correlates of sexual transmission throughout populations, and the growing consideration of structural interventions for HIV/AIDS prevention in DESPR.

While considerable attention in this report has been devoted to HIV/AIDS epidemiology, prevention and treatment, the Workgroup also recognized the importance of NIDA's addressing the **medical consequences of drug use**, including HIV/AIDS infection. Relevant to this report, the medical consequences include a range of infectious and chronic diseases that may affect the progression of HIV infection or, conversely, diseases whose progression HIV may affect. This information contributes to NIDA's efforts to provide a basis for primary prevention of substance abuse, as well as information for clinicians to use in treating substance-using populations. NIDA is uniquely suited to provide this direction and integrative perspective.

As another major program at NIDA, **The National Drug Abuse Treatment Clinical Trials Network (CTN)** was designed to create a bridge between drug abuse researchers and the drug abuse treatment programs, to promote translation of research into practice. While the CTN is being reviewed separately, the Workgroup did have a few concerns that are relevant to the overall review of the NIDA AIDS research program. The CTN was designed to capitalize on an infrastructure of community treatment programs, and to test and implement effective interventions, including HIV prevention interventions, within those programs. As such, the network provides an opportunity to explore the feasibility and effectiveness of a range of approaches appropriate for the context of drug abuse treatment in residential, outpatient, or office-based settings. Thus, the Workgroup was surprised to see (from the materials provided) that the CTN's HIV prevention effort seems to rely solely on refinements of individual-level, cognitive behavioral approaches that were pioneered in the 1980s and early 1990s. The Workgroup believes that the CTN should capitalize on its growing list of HIV behavioral and social science experts to develop and implement a more appropriate array of interventions, for example, those that involve diffusion models and those that focus on structural-level factors. CTN program staff and leadership also should increase their contact with other NIDA Divisions and Centers that sponsor research to develop and test such a range of interventions that might be relevant for the CTN (e.g., DESPR).

The **basic science** portfolio for HIV/AIDS research has an extensive program examining the *in vitro* effects of opioids and, to a lesser extent, cocaine on the immune system. These effects are examined in either the presence or absence of virus in both human and animal models. While the Workgroup appreciates the position that basic science often does not have clear applications and that it is often the nature of basic science to tackle scientific questions that may not have an immediate payoff, this position must be balanced with existing public health priorities. In the context of pressing needs, the Workgroup thought that some areas of basic research were over-represented and should be de-emphasized, and that NIDA does not appear to be focusing on the most important and relevant HIV/AIDS-related questions. Some work on correlations of drugs of abuse with immune system parameters has continued despite consistent epidemiological literature and conferences (*e.g.,* supported by NIDA, the Barcelona AIDS Conference) that suggest a minimal immediate public health relevance for these studies in that clinical and epidemiological correlations have not been demonstrated for these drugs. Immunological impacts of emerging drugs of abuse have been relatively neglected, and it remains an open question as to whether these drugs' immunological effects, if any, are significant. The impact of illicit drugs on HIV/AIDS in the presence of HAART deserves consideration, beyond issues of adherence, because pharmacokinetics studies have indicated intriguing short-term effects and some longer-term results that should be clarified. The neurological effects of advanced HIV/AIDS in the presence of illicit drugs are another area that has been extensively studied, and new directions in this area should be considered.

In the NIDA **intramural research program** (IRP), the Workgroup found that the scope of HIV/AIDS research covered several areas. However, the Workgroup also found that

the research is in many instances duplicative of extramural activities; there is little evidence of cutting-edge research. The Workgroup identified only limited evidence of interactions of the IRP with HIV/AIDS expertise within or outside of NIDA. The IRP could benefit from more input in this area.

5. Translational Research: The Workgroup conceptualized "translational research" as involving two aspects: the translation of basic science findings into public health relevant research or applications, and the translation of research findings from one Division or Center to another. Some points relevant to these concepts are addressed above in the discussion of integrating research and ensuring appropriate staff expertise. From the presentations, it does not appear that NIDA Divisions and Centers sufficiently interact with one another or benefit from each other's expertise to effectively foster translational work in either of the two senses of the word as used here. A proactive effort in some Divisions to ensure translation of basic research to drug abuse applications was evident, and some staff outside CAMCODA has worked with CAMCODA to foster translational work. Nonetheless, the Workgroup concluded that more proactive efforts in translation directed to HIV/AIDS concerns are essential. Translational efforts that incorporate findings from work supported by other NIH components (*e.g.,* mental health, child development, basic biomedical sciences) would benefit NIDA's program and help ensure state-of-the-art questions and approaches. Equally important, translational activities would allow NIDA's expertise and findings to be applied to HIV/AIDS research of other NIH components.

B. Infrastructure, Processes, and Interactions

The interactions of CAMCODA within NIDA and between other Institutes were reviewed and several major findings became evident. NIDA addresses many important HIV/AIDS issues, and the Workgroup identified the issue of NIDA's responsiveness not as primarily a problem of scientific gaps but more as a need to reconsider the processes, such as planning, coordinating, and interacting with others, used in developing science. The primary finding is that interactions are complicated by problems with the structure of CAMCODA, the structure of NIDA, and the planning process for HIV/AIDS research at NIDA.

Overview of Interactions: The presentations by the NIDA Divisions and Centers and NIH Institutes indicated that significant *informal* interaction and coordination occurs across the NIDA Divisions and Centers, with CAMCODA, and between NIDA and the NIH. To a large extent, the interests of the individuals in the extramural program drive *ad hoc* collaborations. In some cases, this reliance on individuals' interests among program staff has resulted in fruitful collaborations; in others, it has resulted in NIDA's absence from potentially useful multi-institute activities.

The presentations also indicated that the NIDA Divisions and Centers and NIH Institutes are active in managing and developing their portfolios. As part of this portfolio management and development process, some NIDA Divisions and Centers at times have worked with CAMCODA to identify research gaps and to effect the transition from basic to applied research. There have been recent efforts by NIDA Division Directors to place

a higher level of emphasis on collaboration and coordination activities in an effort to make collaboration more routine. Less coordination with the NIDA IRP was evident.

Similarly, just as within-NIDA collaboration occurs somewhat sporadically, some collaboration in portfolio development was reported by the presenters from NIMH, NIAID, and NIAAA. All of these indicated that there are very important opportunities for collaboration with NIDA, given the shared interests around co-morbidity and mechanisms of HIV-risk, to name but two.

Overall, the level of joint planning and coordination between CAMCODA and other groups related to HIV/AIDS research is less than optimal, thereby yielding less than optimum progress of science. The larger issue is that there is no NIDA-wide mechanism for collaboration in general and the responsibility for this lies with the NIDA Director. Within this context, a related issue is that CAMCODA does not exercise its responsibility as a convener and coordinator of HIV/AIDS in NIDA. More consistent and intentional efforts to increase the number and quality of interactions are needed.

Functions of CAMCODA: The Workgroup concluded that the combination of CAMCODA's roles as a coordinating entity and as a quasi-division with a separate research portfolio, which sometimes overlaps with those of the divisions, was fraught with difficulty. CAMCODA staff is asked to both develop a portfolio and to assist staff in other divisions to develop their portfolios, resulting, at times, in competition that is not productive in terms of NIDA's overall mission. Indeed, Workgroup members thought that this combination has created problems. For staff involved in epidemiological, social, behavioral, and prevention sciences, the dual demands are particularly problematic. This tension is currently less pronounced for those in the areas of basic sciences and drug abuse treatment development.

CAMCODA's role as a coordinator in NIDA's formal HIV/AIDS planning process is not clear. First, there was no evidence that CAMCODA exercises a convening function to accomplish coordination. In fact, there is no evidence of a workgroup or standing committee within NIDA that extends across all of the Divisions and Centers to manage the identification and prioritization of HIV/AIDS research. There also is not a formal means to allow staff across divisions and centers to share expertise, "brainstorm" scientific ideas, and keep one another informed on scientific issues and activities. Based on the presentations, it was apparent that the process for the coordination of research at NIDA is not institutionalized in a systematic way that allows for the NIDA Divisions and Centers and NIH Institutes to communicate findings and identify priorities in general, or HIV specific. The effect of this deficiency in coordination was evident. Some reports reflected a lack of communication about the content of the portfolios or research results of other NIDA Divisions and Centers. As a result, coordination has been a significant issue. The lack of a formal and ongoing process for collaboration has the potential to hamper the science.

Rather than CAMCODA convening meetings to plan or brainstorm HIV/AIDS research, the Division and Center Directors reported that their ideas for research initiatives are

presented during a spring meeting with the NIDA Director (with other Division and Center Directors present), in which they make a case for their projects. The projects are then either approved or not approved within the NIDA Director's office in a process that was consistently reported as opaque. Some of the Directors reported informal discussions with the CAMCODA Director or his staff before this planning meeting, while others did not report this form of interaction. It does not appear that CAMCODA has a unique role to play as decisions are made for HIV/AIDS program development, priority setting, or funding, nor is the role of CAMCODA as a coordinating center supported by an adequate or appropriate system of communication.

Vertical Communications: The difficulties the Workgroup noted in coordination at the staff level seemed to stem, in part, from over-reliance on "vertical" communications of the Centers and Divisions with the Office of the NIDA Director. This does not provide for sufficient interaction of all Center and Division leadership in a process that conjointly takes advantage of the perspectives of the scientific leadership of the Institute in the Centers and Divisions and the NIDA Director's office, as well as the financial, budgetary, and policy leadership of the Institute. This was most evident in the descriptions of the planning process.

As the first issue in the planning and priority-setting process, it appears that there is an emphasis on "top down" direction. NIDA presenters indicated that advance planning for scientific initiatives begins in the spring for the next fiscal year (*i.e.*, presenters indicated that planning for FY 2004 began earlier in the year and was still underway). This is in marked contrast to reports by other Institutes' staff, where the norm is to develop initiatives two years before the start of the fiscal year (*i.e.,* initiatives for FY 2004 would be planned in 2002). There was also limited information on how the OAR planning process and resultant list of priorities are integrated with NIDA's own planning and priorities. The problems in planning for AIDS funding appear to be symptomatic of a larger problem that affects all of NIDA. NIDA should take this opportunity to adopt a better planning process for the entire Institute.

Coding and Funding of HIV/AIDS Research: Another problem identified was that all NIDA Divisions and Centers consistently reported lack of knowledge or utilization of written guidelines to determine what research is to be coded as AIDS specific or AIDS-related. Questions about the level of exchange between the Office of the NIDA Director and the Director of CAMCODA suggested that input about coding projects as AIDS-specific or AIDS-related from the CAMCODA Director occurs after the funding decisions are made. Division Directors also reported that decisions about categorization of research as AIDS-specific or AIDS-related for funding purposes were *post-facto* in some cases. Decisions related to the use of AIDS dollars were reported to have been made in the Office of the Director, apparently without a systematic process for securing needed input, and the principles that guide the use of AIDS dollars are not clear. Division and Center Directors could not fully describe the process for how AIDS funding decisions are made and reconciled with AIDS coding guidelines.

The process described suggested to the Workgroup that funding was occurring reactively rather than as a result of proactive planning to perform HIV/AIDS research. The Workgroup found that NIDA staff did not regularly and systematically use the guidelines that had been developed in response to the Levine Report; indeed, some staff did not seem aware of the guidelines at all. Consequently, there was no means to update guidelines as the HIV epidemic evolves.

Clear principles are needed for determining the drug abuse interventions that can be funded with AIDS dollars, given the potential role of such interventions in reducing HIV/AIDS transmission and enhancing medical care for persons with HIV/AIDS. A thoughtful, deliberate process needs to be in place that neither codes (and funds) all drug treatment research (or drug abuse prevention research) as AIDS research nor excludes such research from AIDS dollars.

C. CAMCODA's Organization and Management

The presentations and discussions indicated that a number of organizational and management issues interfere with the ability of CAMCODA to carry out its mission in the most efficient manner and to maintain the morale and optimal effectiveness of the CAMCODA staff. The Workgroup recognized that the tensions between being a coordinating entity and a quasi-division certainly pose management challenges for the leadership of CAMCODA, as they would for anyone, and that the concerns discussed above about NIDA's overall planning process present other challenges. However, the Workgroup concluded that organizational and management practices internal to CAMCODA operate with the above-noted concerns to interfere with CAMCODA's ability to foster and support state-of-the-art science addressing the most pressing questions.

A consistent theme from many sources (NIDA and non-NIDA) indicated a lack of transparency and formal mechanisms for communication among and with CAMCODA staff. The processes and priorities for making decisions within CAMCODA are not clear to staff of the Center, and staff expertise and input are not optimally utilized. The means of ensuring, when possible, staff concurrence with decisions and understanding decisions when concurrence is not possible need improvement. For example, there is not a shared understanding within CAMCODA as to why the Director of CAMCODA has placed an emphasis in the Caribbean. It also is not clear why there is interest in certain other international research where it does not seem that the HIV/AIDS epidemic in those countries is linked closely to drug abuse (even though one of the initiatives was reported as not coming from CAMCODA).

The presentations, interviews, and written materials provided some examples to Workgroup members of specific concerns related to the internal management process in CAMCODA. These include (1) regular and effective internal planning and management meetings do not appear to be held with adequate regularity, and there is no other mechanism to secure staff input and foster communication; (2) morale among CAMCODA staff appears to be low; (3) it does not appear that the strengths of all the staff with knowledge of HIV/AIDS are sufficiently utilized; and (4) decisions are

communicated without ensuring staff understanding of the reasoning, thereby giving the decisions an arbitrary appearance or connotation of "favoritism."

Some Workgroup members were concerned that the most senior leadership of CAMCODA is not expert in the behavioral and social sciences that are key components of NIDA's HIV/AIDS program. Without the leadership's having that expertise, it becomes even more critically important to effectively secure and use the skills of those staff that are trained in behavioral and social sciences.

No other Division appears to be focused on medical consequences of drug abuse from a clinical perspective, and CAMCODA is strong in this area. The Workgroup concluded that an organizational structure housing all activities related to medical consequences of drug abuse, including but not limited to HIV/AIDS, was reasonable and that medical consequences of drug abuse should continue to be housed in a separate entity. This finding is not intended to decrease support for HIV/AIDS issues, which remain very challenging and compelling, but to highlight the inter-relatedness of various clinical consequences of drug abuse and the need for NIDA experts who recognize that inter-relatedness and complexity.

III. Recommendations

A. Research Priorities and Future Directions

The Workgroup made the following recommendations with regard to the research priorities and future directions of the research portfolio:

Maintaining a Responsive Portfolio

- NIDA should create a vision for the research portfolio that mirrors the direction of the HIV/AIDS epidemic among drug-using populations and the prevention and treatment needs of the populations affected. NIDA's HIV/AIDS research should be consistent with and responsive to epidemiological findings relating to the roles of drug abuse and associated behaviors in the HIV epidemic, and should incorporate various perspectives about the determinants, prevention and treatment of the disease, including biomedical, behavioral, and social approaches. Interdisciplinary approaches should be encouraged.

- NIDA's international HIV/AIDS research should be responsive to the priorities identified in NIDA's planning documents as well as OAR planning documents. International research should emphasize areas where the HIV/AIDS epidemic intersects with drug abuse, such as currently seen in Russia, Eastern Europe, and Southeast Asia, but also should address areas with emerging and potential epidemics related to drug abuse.

- NIDA should de-emphasize, and consider eliminating, duplicative research, *i.e.,* research that in its essence addresses scientific questions that most consider resolved, research that has already been conducted, and research that does not

seem likely to provide new and useful knowledge because of its similarity to other work. Examples include many studies of the impact of opiates and cocaine on the untreated natural history of the disease and *in vitro* studies of these drugs on HIV replication.

- NIDA should strengthen its mechanisms for HIV/AIDS translational research, *i.e.,* the movement of basic research findings toward public health applicability and the applicability of findings in one program area to another. A NIDA-wide planning and coordinating process should attend specifically to the issue of translational research in HIV/AIDS (for example, a coordinated "pipeline" for development of basic biological and social science findings to testing of interventions to evaluating effectiveness in practice settings).

Recommendations for Specific Areas of Emphasis

- The prevention of HIV transmission and the development of AIDS associated with drug use among youth, adolescents, and young adults, integrating findings from behavioral epidemiology studies of risk and protective factors in these groups, cognitive science findings on risk-assessment and responses to risk, and findings about the natural history of drug use and addiction. Such studies should recognize that drug abuse and HIV/AIDS risk do not exist in isolation but occur in a context of other sexually transmitted diseases, maladaptive behaviors, and environmental factors that may point to targets of intervention or suggest intervention methods.

- The role of illicit drug use on sexual risk behavior, *i.e.,* prevention research that targets risk reduction by addressing social and cognitive factors in decision-making among youth while under the influence.

- The relationship between HIV/AIDS medication adherence and relapse to higher risk behaviors among HIV infected drug users. Research should include strategies to increase medication adherence, particularly in recovering populations at high risk for relapse to drug abuse and risky sexual behaviors.

- Model and intervention development for HIV/AIDS prevention that extends beyond individual and network levels of analysis and incorporates social level units of analysis (*e.g.,* families –defined as a network of mutual support, neighborhoods, institutions, and communities), as well as structural intervention concepts.

- Pharmacokinetic studies of an ever evolving list of anti-retroviral medications in the presence of new and emerging drugs of abuse as well as existing and new treatments for drug abuse, and corresponding coordination of these studies with clinical epidemiological investigation about longer term effects in clinical populations.

- Research responsive to technological advances, such as the applicability and impacts of new HIV/AIDS diagnostic and treatment technologies as they apply to drug abuse treatment and prevention. Conversely, the applicability and impacts of advances in drug abuse treatment and prevention technologies as they may apply to HIV/AIDS concerns.

- Co-infections and HIV/AIDS treatment in substance users.

- Basic science, such as acute/chronic substance use on immune function for emerging drugs of abuse. Where possible, studies should focus on human immunology, not animal models or cell culture studies.

- Drug combinations (Viagra and methamphetamines) and related risk behaviors.

- Additional research in medications development, which could make a significant contribution in the ability to prevent HIV transmission and progression to AIDS.

- Studies that address the role that advances in pharmacologic management of drug abuse, such as the use of Buprenorphine, other anti-addiction medications, and "office-based" treatment, can have in treatment of HIV seropositive drug abusers.

- Research on improved ways to identify, treat, and counsel HIV seropositive drug users, their families, and their networks in different settings. For example, at the individual level, studies of the utility and impacts of rapid testing for HIV/AIDS in treatment centers and other settings in which drug abusers are encountered could be conducted.

- Research on the medical aspects and consequences of drug abuse, and the effects of illicit drugs at different stages of human development.

B. Structure and Process for Coordination

The Workgroup made the following recommendations with regard to NIDA's structure and processes for coordination:

- The coordination of the HIV/AIDS program should be housed outside the Divisions and Centers. There should be an HIV/AIDS Coordinator in the NIDA Office of the Director with the authority and responsibility to coordinate the HIV/AIDS research program across the Institute, including the IRP. The role of the HIV/AIDS Coordinator would be to manage the development and implementation of an integrated, forward-looking HIV/AIDS research program in close collaboration with the directors of the Divisions and Centers. The Workgroup recommends that this position be sufficiently senior and infused with sufficient authority to accomplish this role.

- NIDA should establish an administrative entity, with a focus on the medical consequences of drug use, including HIV/AIDS, neurological and other clinical

dimensions of drug use generally. The Workgroup believes that the structure and organizational location of this entity should be left to the discretion of the NIDA Director as she considers the best administrative options for establishing the entity.

- Each NIDA Division and Center should develop a mission statement that clearly articulates how the HIV/AIDS program fits within the mission of each division and center. The mission statements should be used for planning purposes and for providing guidance to the extramural community.

- NIDA should institute a planning process that ensures collaboration among all of the Divisions, Offices, and Centers at all stages, including the development of new initiatives submitted to the OAR. NIDA's HIV/AIDS Coordinator should manage the planning process, which must place value on inter-disciplinary, inter-division, and inter-institute collaboration and interaction. NIDA leadership should reward collaboration.

- All Divisions should make it a priority to acquire and maintain access to HIV/AIDS expertise, either through development of their own staff or collaborations with staff in other Divisions or Institutes, as appropriate for the scientific goals of the programs.

- NIDA's IRP should work to increase its interactions with other Institute staff with HIV/AIDS expertise to secure an HIV/AIDS forward looking, cutting-edge portfolio.

- NIDA should redouble its efforts to stimulate interactions among extramural researchers whose primary focus is drug abuse and those whose primary focus is HIV/AIDS.

- The Director of NIDA is encouraged to work with the Director of OAR and other Institutes' Directors to identify the best mechanisms for facilitating cross-institute collaboration and communication, *e.g.,* OAR coordinating committees. Collaboration with and utilization of existing NIH HIV/AIDS research networks should increase. Clearly negotiated roles and methods of ensuring NIDA's input into NIH-wide networks and initiatives should be established, commensurate with NIDA's commitment to and investment in trans-NIH activities.

- NIDA should institute a policy to ensure that HIV/AIDS resources are spent on forward-looking research that is responsive to the epidemiology of HIV/AIDS, updated HIV diagnostic, prevention and treatment developments, and research findings from other relevant areas.

- NIDA should review and update its policy to determine the projects that qualify for HIV/AIDS research funding. The Levine Report should be consulted and NIDA should provide updated explicit policy guidelines regarding how a project's

eligibility for HIV/AIDS funds will be determined. Eligibility should relate to a project's plans to make meaningful and significant contributions to HIV/AIDS research and to ensure that HIV/AIDS components are fully integrated. The guidelines should be made known to all NIDA staff and to all grantees.

- In recognition that basic research not obviously related to HIV/AIDS may, in the future, be important to advancing an understanding of HIV/AIDS, NIDA should negotiate with OAR to establish, *a priori*, mutual understanding of and agreement to principles guiding use of AIDS funds that may be spent on basic research. Justifications, perhaps based on the nature of the research or percentage guidelines, for those expenditures should be developed and made available to staff and the research community.

Appendices

Appendix 1

Agenda
NIDA Council Workgroup on HIV/AIDS Research
NIDA 3rd Floor Conference Room

September 3, 2003

9:00-9:15	Introductions and Call to Order David Vlahov, Ph.D., Chair William C. Grace, Ph.D., Deputy Director, Office of Extramural Affairs
9:15-9:45	Executive Session: Review Objectives, Process, Content of Briefing Book
9:45-10:30	Center on AIDS and Other Medical Consequences of Drug Abuse (CAMCODA): Overview of "Office of AIDS" functions Henry ("Skip") Francis, M.D., Director
10:30-10:45	Break
10:45-11:30	Center on AIDS and Other Medical Consequences of Drug Abuse (CAMCODA): Overview of "Research Division" Functions Henry ("Skip") Francis, M.D., Director
11:30-12:15	Division of Neuroscience and Basic Research (DNBR) David Shurtleff, Ph.D., Acting Director
12:15-1:00	Lunch (working)
1:00 – 1:45 AND 1:15 – 1:45	Meetings with individual staff Development of Comments on Vision and Priorities of Division of Neuroscience and Basic Research or the Intramural Program.
1:45-2:15	National Institute of Allergy and Infectious Diseases (NIAID) Jonathan Kagan, Ph.D., Deputy Director, Division of AIDS
2:15-2:45	National Institute of Mental Health (NIMH) Ellen Stover, Ph.D., Director, Division of Mental Disorders, Behavioral Research and AIDS
2:45-3:00	Break

3:00-3:30	National Institute on Alcohol Abuse and Alcoholism (NIAAA) Kendall Bryant, Ph.D., Chief, Collaborative and Special Health ProgramsTeam: Scientific Coordinator HIV/AIDS Research
3:30-4:00	Nora Volkow, M.D., Director, NIDA
4:00-4:45	Division of Treatment Research and Development (DTRD) Frank Vocci, Ph.D., Director
4:45-5:00	Executive Session: Review notes from day, identify themes detected, and develop new questions.

September 4th

9:00- 9:45	Center for the Clinical Trials Network (CTN) Jack Blaine, M.D., Deputy Director
9:45-10:30	Division of Epidemiology, Prevention, & Services Research (DESPR) Wilson Compton, M.D., Director
10:30-12:00	Executive Session Summary
12:00-1:00	Lunch
1:00-2:00	Provisional summary, plan for follow-up conference calls or meetings

Appendix 2

Roster
National Advisory Council on Drug Abuse
Workgroup on HIV/AIDS
September 3-4
Neurosciences Center
3rd Floor NIDA Conference Room (Room 3103)
Rockville, MD

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